REMARKS/ARGUMENTS

Reconsideration of the above-identified application, in view of the following remarks, is respectfully requested.

I Certified Copy Of Danish Priority Document PA 1999 01279

In the Office Action Summary, the Examiner has indicated that none of the certified priority documents have been received by the U.S. Patent and Trademark Office. A certified copy of the Danish priority Application No. PA 1999 01279 was filed with the USPTO on June 13, 2001. Applicants enclose herewith a copy of the postcard stamped by the PTO showing receipt of the claim for priority and the '279 priority document.

Applicants respectfully request that the Examiner acknowledge receipt of the '279 priority document in the next Office Action.

II Election of Species Requirement

The Examiner has acknowledged applicant's election of the inhibitor 5-(5-methoxy-1,3-dioxo-1,3-dihydro-isoindol-2-ylmethyl)-2-oxalyl-amino -4,7-dihydro-5H-thieno-[2,3-c]pyran-3 carboxylic acid. The Examiner has withdrawn claims 14, 15, 19, 24, and 25 from prosecution pursuant to 27 C.F.R. § 1.142(b) as covering non-elected species.

Applicants respectfully request that the Examiner withdraw the election of species requirement upon allowance of a generic claim.

III Amendments to the Specification

The specification has been amended to claim priority to U.S. Serial No. 09/628,490, and all of the applications to which it claims priority. Since this application was filed before November 29, 2000, the time period in rule 78(a)(2)(ii) does not apply to this application. See 37 C.F.R. § 1.78(a)(2)(ii)(B). Since certified copies of the Danish Patent Application Nos. 0344/98, PA 1998

00480, PA 1998 00938, PA 1998 01385, and PA 1998 01612, were submitted in U.S. Serial No. 09/268,490, applicants respectfully submit that certified copies of these applications do not need to be submitted in this application.

IV Status Of The Claims

Claims 1-10 and 28 have been amended.

Claims 1 and 2 have been amended to incorporate the corrections requested by the Examiner on page 7 of this Office Action. Claim 28 has been amended to recite the compound of Formula I. Claims 1-10 have been amended to recite "at least one PTPase in which said inhibition is intended", as suggested by the Examiner in a telephone call to Applicant's representative, John C. Todaro, on April 16, 2003. Claims 1-6 have been amended to correct typographical errors. Support for these amendments may be found in the specification at page 34, lines 25-30, page 35, lines 4-7 and 31-34, page 63, line 1 to page 65, line 13. No new matter has been added by these amendments.

Claims 14, 15, 19, 24, and 25 have been withdrawn by the Examiner. Claims 1-13, 16-18, 20-23, and 26-31 are currently at issue.

V Rejections under 35 U.S.C. § 112

(i) Claims 1-13, 16-18, 20-23, and 26-31 stand rejected under 35 U.S.C. § 112, first paragraph, for lack of enablement. The Examiner acknowledges that the claims are enabled for the inhibition of PTPases by inhibitors having a carboxyl substituted thienyl core and an oxalo side group, but asserts that the specification "does not reasonably provide enablement for the use of inhibitors as broadly recited by purely functional characteristics." The Examiner also asserts that the specification does not enable use of the inhibitors for autoimmune diseases or cancers.

At pages 2-6 of the Office Action, the Examiner sets forth the *In re Wands* factors, and concludes that the specification would not enable one skilled in the art to practice the invention without undue experimentation. The Examiner states at page 5 of the Office Action that the

working examples of the specification, at pages 299-307, are "merely . . . generalized activity assays on a few select inhibitors (all having a carboxyl-substituted thienyl core and an oxalo side group)." The Examiner therefore concludes that "[t]he facts in this case demonstrate that, beyond the particular inhibitors of the working examples and closely related analogs thereof, all Applicants have is a 'mere wish or plan' to uncover PTPase inhibitors which they currently do not have in their possession."

This rejection is respectfully traversed. Contrary to the Examiner's assertion, the specification provides adequate teachings for one skilled in the art to practice the claimed invention.

The present claims are directed to a method of inhibiting intracellular or membrane-associated PTPases having an aspartic acid (Asp) in position 48 using the numbering for PTP1B, by exposing the PTPase to an inhibitor compound that possesses certain structural, physico-chemical and spatial characteristics.

According to the current law and patent practice, the specification can permit some inferences to be drawn by those skilled in the art, and still comply with the enablement and written description requirements. In other words, there is no requirement that the claims be restricted to the working examples. Section 2164.03 of MPEP recites:

> the scope of the required enablement varies inversely with the degree of predictability involved, but even in unpredictable arts, a disclosure of every operable species is not required (*In re Vaeck*, 947 F.2d 488, 496 & n.23, 20 USPQ2d 1438, 1445 & n.23 (Fed. Cir., 1991); *In re Vickers*, 141 F.2d 522, 526-27, 61 USPQ 122, 127 (CCPA 1944); *In re Cook*, 439 F.2d 730, 734, 169 USPQ 298, 301 (CCPA 1971))

As further stated in section 2164.08 of MPEP:

> claims are not rejected as broader than the enabling disclosure under 35 U.S.C. 112 for non-inclusion of limitations dealing with factors which must be presumed to be within the level of ordinary skill in the art; the claims need not recite such factors where one of ordinary skill in the art to whom the specification and claims are directed would consider them obvious (*In re Skrivan*, 427 F.2d 801, 806, 166 USPQ 85, 88 (CCPA 1970))... When analyzing the enabled scope of a claim, the teachings

> of the specification must not be ignored because claims are to be given their broadest reasonable interpretation that is consistent with the specification.

See also *Application of Angstadt* (537 F.2d 498, 502-503, 190 USPQ 214, 218 [Cust. & Pat.App., 1976]) stating that applicants "are not required to disclose every species encompassed by their claims even in an unpredictable art." Similarly, in *In re Rasmussen*, court stated that "a claim may be broader than the specific embodiment disclosed in a specification" (650 F.2d 1212, 1215, 211 USPQ 323, 326 [Cust. & Pat.App., 1981]). Finally, in *In re Goffe* (542 F.2d 564, 567, 191 USPQ 429, 431 [CCPA 1976]), the court stated:

> To provide effective incentives, claims must adequately protect inventors. To demand that the first to disclose shall limit his claims to what he has found will work or to materials which meet the guidelines specified for "preferred" materials in a process such as the one herein involved would not serve the constitutional purpose of promoting progress in the useful arts.

Examples 121 and 122 on pages 299-306 of the specification provide a method for identifying substrates that are specifically dephosphorylated by PTPases that are inhibited by the compounds disclosed in the specification. Once such substrates have been identified using the method disclosed in Example 121, one of ordinary skill in the art would readily recognize those conditions, such as autoimmune diseases, acute and chronic inflammation, osteoporosis, cancers, type I diabetes, type II diabetes, and obesity, in which the substrates thus identified are involved. Indeed, the present specification discloses numerous references that teach various conditions that are associated with PTPases (see "Summary Of Background Section" on pages 15-16 of the present specificaiton).

Example 123 on pages 306-307 of the specification clearly describes a method for analyzing the blood glucose lowering effects of all the compounds of the invention, not just those having a carboxyl-substituted thienyl core and an oxalo side group, as asserted by the Examiner. This is a key assay that provides a way of assaying substrates at the functional level.

Applicants need not provide working examples for all embodiments of the invention. The Examiner, moreover, has mis-characterized the level of guidance present in the instant specification, overstated the amount of experimentation required to determine specific PTPase inhibitors and underestimated the level of skill in the art

Furthermore, at page 4 of the Office Action, the Examiner relies on statements in the specification that the application covers "development candidates" or "prototype drugs." However, the law is clear that FDA approval is not necessary to support the utility of claims covering a pharmaceutical compound. *See, e.g., In re Brana*, 34 USPQ2d 1436, 1442-43 (Fed. Cir. 1995), in which the Court stated that "usefulness in patent law, and in particular in the context of pharmaceutical inventions, necessarily includes the expectation of further research and development." *Id.*

Accordingly, in view of the arguments set forth above, applicants believe that claims 1-13, 16-18, 20-23, and 26-31 are fully enabled by the specification, and respectfully request that this rejection be withdrawn.

(ii) Claims 1-3, and 28-31 stand rejected under 35 U.S.C. § 112, second paragraph, for indefiniteness.

Applicants have amended claims 1-3 as requested by the Examiner, and have amended claim 28 to include Formula I. Accordingly, applicants believe that this rejection has been overcome, and respectfully request that the rejection be withdrawn.

VI Rejection under 35 U.S.C. § 102

Claims 1-13, 16-18, 20-23, and 26-31 stand rejected under 35 U.S.C. § 102(e) as anticipated by Moller *et al.* (U.S. Patent No. 6,262,044, "the '044 Patent").

Applicants have amended this application to claim the benefit of the application which matured into U.S. Patent No. 6,262,044 (i.e., U.S. Serial No. 09/268,490). Therefore, U.S. Patent No. 6,262,044 is not a reference under 35 U.S.C. § 102(e) to this application.

Accordingly, applicants respectfully request that the rejection be withdrawn.

VII Obviousness-Type Double Patenting Rejection

Claims 1-13, 16-18, 20-23 and 26-31 stand rejected under the judicially created doctrine of obviousness-type double patenting over claims 9 and 10 of the '044 Patent. The Examiner concedes that the conflicting claims are not identical, but asserts that they are not patentably distinct from each other because the prior art claims various inhibitors within the scope of the present claims. The Examiner cites a comparison of claims 1 and 7 of the '044 Patent with claims 26 and 27 of the present application, and concludes that it would have been obvious that the various functional characteristics recited in the present claims would be inherent to the conflicting inhibitors, motivated by the recognition that the same compounds are being used for the same end purpose (PTPase inhibition).

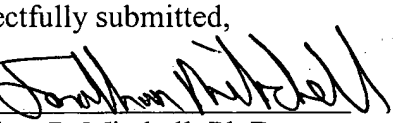
This rejection is respectfully traversed, on the grounds that the claims of the '044 Patent are directed to compounds wherein group A in the compound of Formula (I) is a 4,5,6,7-tetrahydro-thieno derivative. Accordingly, the claims of the '044 Patent do not encompass compounds with a 4,7-dihydro-5*H*-thieno[2,3-c]pyran-3-carboxylic acid core, as is present in the elected species, and as a result there is no overlap with the elected species, namely 5-(5-methoxy-1,3-dioxo-1,3-dihydro-isoindol-2-ylmethyl)-2-oxalyl-amino-4,7-dihydro-5H-thieno-[2,3-c]pyran-3 carboxylic acid.

Since Group A of claim 1 of the '044 Patent does not cover the 4,7-dihydro group, applicants believe that the Examiner's rejection of claims 1-13, 16-18, 20-23 and 26-31 on obviousness-type double patenting grounds over the '044 Patent is in error, and respectfully request that this rejection be withdrawn.

In view of the foregoing remarks, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue.

Dated: October 22, 2003

Respectfully submitted,

By 

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